The following corrections or additions to the January 2004 list were published in the Federal Register in March 2004.

New Approvals

NADA Number: 141-223

Trade Name:	Clinacox™ / 3-Nitro®
Ingredients:	Diclazuril, roxarsone
Sponsor:	Alpharma, Inc.
Approval Date:	January 27, 2004
Status:	Over-the-counter
Route:	Oral, via feed
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feed.
Concentration:	Diclazuril – 0.2 percent activity per pound of Type A Medicated Article; Roxarsone – 10, 20, 50 or 80 percent activity per pound of Type A Medicated Article.
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunette, E. mitis (mivati),* and *E. maxima*. Also, for increased rate of weight gain, improved feed efficiency, and improved pigmentation.
Tolerance:	21CFR 556.185 Diclazuril: Tolerances for parent diclazuril have been established as follows: 0.5 part per million in muscle, 1 part per million in skin/fat, and 3 parts per million in liver. 21CFR 556.60 Arsenic: The tolerances for total residues of combined arsenic are established as 0.5 part per million in uncooked muscle tissue and eggs and 2 parts per million in uncooked edible-by-products.
Withdrawal:	5 days

21CFR 558.198

NADA Number: 141-224

Trade Name:	Optaflexx™ / Rumensin® / Tylan®
Ingredients:	Ractopamine hydrochloride, monensin sodium, tylosin phosphate
Sponsor:	Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date:	January 27, 2004
Status:	Over-the-counter
Route:	Oral via feed
Species:	Cattle (fed in confinement for slaughter)
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Ractopamine hydrochloride – 9 or 45 grams activity per pound of Type A Medicated Article; monensin sodium – 20, 30, 45, 60, 80 or 90.7 grams activity per pound of Type A Medicated Article; tylosin phosphate – 40 or 100 grams activity per pound of Type A Medicated Article.
Indications:	Increased rate of weight gain, improved feed efficiency, increased carcass leanness, prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*, and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.
Tolerance:	21CFR 556.570 Ractopamine: The tolerance for residues of ractopamine hydrochloride in edible cattle tissues (muscle) is 0.03 part per million and 0.09 part per million in liver. 21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in edible tissues. 21CFR 556.740 Tylosin: The tolerance established for negligible residues is 0.2 part per million in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days
Patent number:	4,690,951 Expiration date: September 1, 2007 5,643,967 July 1, 2014

21CFR 558.500, 558.355 & 558.625

NADA Number: 141-225

Trade Name:	Optaflexx™ / Rumensin®
Ingredients:	Ractopamine hydrochloride, monensin sodium
Sponsor:	Elanco Animal Health A Division of Eli Lilly & Co.
Approval Date:	January 27, 2004
Status:	Over-the-counter
Route:	Oral via feed
Species:	Cattle (fed in confinement for slaughter)
Drug Form:	Type A Medicated Articles to make Type B and Type C medicated feeds.
Concentration:	Ractopamine hydrochloride – 9 or 45 grams activity per pound of Type A Medicated Article; monensin sodium – 20, 30, 45, 60, 80 or 90.7 grams activity per pound of Type A Medicated Article.
Indications:	Increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii* in cattle fed in confinement for slaughter for the last 28 to 42 days on feed.
Tolerance:	21CFR 556.570 Ractopamine: The tolerance for residues of ractopamine hydrochloride in edible cattle tissues (muscle) is 0.03 part per million and 0.09 part per million in liver. 21CFR 556.420 Monensin: A tolerance of 0.05 part per million is established for negligible residues in edible tissues.
Withdrawal:	Zero days
Patent number:	4,690,951 Expiration date: September 1, 2007 5,643,967 July 1, 2014

21CFR 558.500 & 558.355

NADA Number: 141-226

Trade Name:	Aviax™ / Stafac® / 3-Nitro®
Ingredients:	Semduramicin, virginiamycin, roxarsone
Sponsor:	Phibro Animal Health
Approval Date:	February 23, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Broiler chickens
Drug Form:	Type A Medicated Articles to make Type C medicated feed.
Concentration:	Semduramicin: 22.7 grams activity per pound of Type A Medicated Article; Virginiamycin: 5, 10, 20, 50 or 227 grams activity per pound of Type A Medicated Article; Roxarsone: 10, 20, 50 or 80 percent activity per pound of Type A Medicated Article
Indications:	For the prevention of coccidiosis caused by *Eimeria tenella, E. acervulina, E. maxima, E. brunetti, E. necatrix,* and *E. miva (E. mitis)*, for the prevention of necrotic enteritis caused by *Clostridium perfringens* susceptible to virginiamycin, for increased rate of weight gain and improved feed efficiency, and improved pigmentation.
Tolerance:	21CFR 556.597: Semduramicin: Tolerances are established for residues of parent semduramicin in uncooked edible tissues of 400 parts per billion in liver and 130 parts per billion in muscle. 21CFR 556.750: Virginiamycin: No tolerance required. 21CFR 556.60 Roxarsone: Tolerance for residues of arsenic from roxarsone are established at 0.5 part per million in uncooked muscle tissue, 2 parts per million in uncooked edible by-products, and 0.5 part per million in eggs.
Withdrawal:	5 days

21CFR 558.555 & 558.635

NADA Number: 141-227

Trade Name:	UlcerGard™
Ingredients:	Omeprazole
Sponsor:	Merial Ltd.
Approval Date:	February 18, 2004
Status:	Over-the-counter
Route:	Oral
Species:	Equine
Drug Form:	Paste
Concentration:	37% weight/weight (w/w)
Indications:	For the prevention of gastric ulcers.
Patent number:	5,708,017 Expiration date: April 4, 2015
Exclusivity:	3 years

21CFR 520.1615

ANADA Number: 200-307

Pioneer Product:	055-060
Trade Name:	Penicillin G Potassium, USP
Ingredients:	Penicillin G potassium
Sponsor:	Vétoquinol N.-A., Inc.
Approval Date:	January 29, 2004
Status:	Over-the-counter
Route:	Oral, via drinking water
Species:	Turkeys
Drug Form:	Powder (soluble)
Concentration:	0.5 billion units per 324 gram jar
Indications:	For the treatment of erysipelas caused by *Erysipelothrix rhusiopathiae.*
Tolerance:	21CFR 556.510 Penicillin: The tolerance established for penicillin and salts of penicillin residues in the uncooked edible tissues is 0.01 part per million.
Withdrawal:	1 day

21CFR 520.1696b

ANADA Number: 200-345

Pioneer Product:	046-109
Trade Name:	Lincomycin - Spectinomycin
Ingredients:	Lincomycin hydrochloride monohydrate, spectinomycin dihydrochloride pentahydrate
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	February 5, 2004
Status:	Over-the-counter
Route:	Oral (drinking water)
Species:	Chickens (up to 7 days old)
Drug Form:	Powder (soluble)
Concentration:	16.7 grams lincomycin and 33.3 grams spectinomycin per foil pouch
Indications:	For use in chickens up to 7 days of age as an aid in the control of air sacculitis caused by either *Mycoplasma synoviae* or *Mycoplasma gallisepticum* susceptible to lincomycin-spectinomycin and Complicated Chronic Respiratory Disease (Air Sac Infection) caused by *Escherichia coli* and *M. gallisepticum* susceptible to lincomycin-spectinomycin.
Tolerance:	21CFR 556.360 Lincomycin: The tolerance established for residues of lincomycin in chickens is not required. 21CFR 556.600 Spectinomycin: The tolerance established for negligible residues of spectinomycin in the uncooked edible tissues of chickens is 0.1 part per million.
Withdrawal:	None stated.

21CFR 520.1265

ANADA Number: 200-351

Pioneer Product:	034-025
Trade Name:	Lincomycin Injectable, USP
Ingredients:	Lincomycin hydrochloride monohydrate
Sponsor:	Phoenix Scientific, Inc.
Approval Date:	February 13, 2004
Status:	Over-the-counter
Route:	Intramuscular
Species:	Swine
Drug Form:	Liquid (solution)
Concentration:	25, 100, and 300 milligrams per milliliter
Indications:	For the treatment of infectious forms of arthritis caused by organisms sensitive to its activity. This includes most of the organisms responsible for the various infectious arthritides such as *Staphylococci*, S*treptococci*, *Erysipelothrix* and *Mycoplasma* spp. It is also indicated for the treatment of mycoplasma pneumonia.
Tolerance:	21CFR 556.360 Lincomycin: Tolerances of 0.6 part per million in liver and 0.1 part per million in muscle are established for lincomycin residues.
Withdrawal:	2 days

21CFR 522.1260

Supplemental Approvals

This section displays the change(s) to the original approval. To read the complete approval please refer to 21CFR Parts 500 and the related Federal Register notices.

NADA Number: 112-051

This supplemental application provides for combining NADA 112-050 and NADA 112-051 into 112-051, and revising the description of various parasites in the labeling.

Trade Name:	Levasole®
Ingredients:	Levamisole hydrochloride
Sponsor:	Schering-Plough Animal Health Corp.
Approval Date:	December 23, 2003
Status:	Over-the-counter
Route:	Oral
Species:	Cattle, sheep
Drug Form:	Powder (soluble)
Concentration:	11.7 grams in the 0.46 oz packet, 46.8 grams in the 1.8 oz packet, and 544.5 grams in the 21.34 oz bottle
Indications:	Used for the following adult nematode infections: **Sheep:** Stomach Worms: *Haemonchus contortus, Trichostrongylus axei, Teladorsagia circumcincta.* Intestinal Worms: *Trichostrongylus colubriformis, Cooperia curticei, Nematodirus spathiger, Bunostomum trigonocephalum, Oesophagostomum columbianum, Chabertia ovina.* Lungworms: *Dictyocaulus filaria.* **Cattle:** Stomach Worms**:** *Haemonchus placei, Ostertagia ostertagi, Trichostrongylus axei.* Intestinal Worms: *Trichostrongylus longispicularis, Cooperia oncophora, Cooperia punctata, Nematodirus spathiger, Bunostomum phlebotomum, Oesophagostomum radiatum.* Lungworms: *Dictyocaulus viviparus.*
Tolerance:	21CFR 556.350 Levamisole: A tolerance of 0.1 part per million is established for negligible residues in the edible tissues.
Withdrawal:	Cattle - 2 days Sheep - 3 days

21CFR 520.1242(a)

ANADA Number: 200-221

This supplemental application provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone acetate and estradiol.

Trade Name:	Component® TE-IS with Tylan®
Ingredients:	Trenbolone acetate, estradiol, tylosin tartrate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	February 13, 2004
Status:	Over-the-counter
Route:	Subcutaneous (ear)
Species:	Cattle (steers fed in confinement for slaughter)
Drug Form:	Implant
Concentration:	Each implant contains 80 mg trenbolone acetate, 16 mg estradiol, and 29 mg tylosin tartrate.
Indications:	For increased rate of weight gain and improved feed efficiency.
Tolerance:	21CFR 556.739 Trenbolone: Tolerance for residues is not needed. 21CFR 556.240 Estradiol: No residues of estradiol or any of the related esters are permitted in the uncooked edible tissues in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver. 21CFR 556.740 Tylosin: Tolerances are established for residues of tylosin in edible products in cattle as 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days
Patent Number:	5,874,098 Expiration Date: May 28, 2017
Exclusivity:	3 years

21CFR 522.2477

ANADA Number: 200-346

This supplemental application provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone and estradiol.

Trade Name:	Component® TE-IH with Tylan®
Ingredients:	Trenbolone acetate, estradiol, tylosin phosphate
Sponsor:	Ivy Laboratories, Division of Ivy Animal Health, Inc.
Approval Date:	February 23, 2004
Status:	Over-the-counter
Route:	Subcutaneous (ear)
Species:	Cattle (heifers fed in confinement for slaughter)
Drug Form:	Implant
Concentration:	Each implant contains 80 mg trenbolone acetate, 8 mg estradiol, and 29 mg tylosin tartrate.
Indications:	For increased rate of weight gain.
Tolerance:	21CFR 556.739 Trenbolone: Tolerance for residues is not needed. 21CFR 556.240 Estradiol: No residues of estradiol or any of the related esters are permitted in the uncooked edible tissues in excess of the following increments above the concentrations of estradiol naturally present in untreated animals: 120 parts per trillion for muscle, 480 parts per trillion for fat, 360 parts per trillion for kidney, and 240 parts per trillion for liver. 21CFR 556.740 Tylosin: Tolerances are established for residues of tylosin in edible products in cattle as 0.2 part per million (negligible residue) in uncooked fat, muscle, liver, and kidney.
Withdrawal:	Zero days
Patent Number:	5,874,098 Expiration Date: May 28, 2017
Exclusivity:	3 years

21CFR 522.2477

Suitability Petition Action

Number:	04P-0058/WDL1
Sponsor:	Cross Vetpharm Group, Inc.
Petition:	Request permission to withdraw petition to file an ANADA for a generic new animal drug phenylbutazone which differs from the pioneer product, Butatron®, Cross Vetpharm Group, Inc., NADA 044-756 by the following characteristic(s): The generic product will have a different physical form, powder, whereas the pioneer approved product is a tablet.
Action:	Acknowledged on March 4, 2004.

Number:	03P-0552/CP1
Sponsor:	Jurox PTY, Limited
Petition:	Request permission to file an ANADA for a generic new animal drug carprofen which differs from the pioneer product, Rimadyl® Caplets, Pfizer, Inc., NADA 141-053 by the following characteristic(s): The generic product will have a different dosage form (liquid) and different strength (concentration) from the pioneer.
Action:	Approved on March 19, 2004.

Number:	04P-0127/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug clindamycin hydrochloride which differs from the pioneer product, Antirobe®, Pharmacia & Upjohn Co., NADA 120-161 by the following characteristic(s): The generic product will have a different dosage form (tablet) and different strength (concentration) from the pioneer.
Action:	Filed on March 16, 2004.

Number:	04P-0128/CP1
Sponsor:	Smart Drug Systems, Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug amoxicillin trihydrate/clavulanate potassium which differs from the pioneer product, Clavamox® Tablets, Pfizer Inc., NADA 055-099 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Filed on March 16, 2004.

Number:	04P-0032/CP1
Sponsor:	Pennfield Oil Co.
Petition:	Request permission to file an ANADA for a generic new animal drug chlortetracycline/sulfamethazine which differs from the pioneer product, Aureo S 700®, Alpharma, Inc., NADA 035-805 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Approved on March 24, 2004.

Number:	04P-0136/CP1
Sponsor:	Intervet Inc.
Petition:	Request permission to file an ANADA for a generic new animal drug florfenicol which differs from the pioneer product, Nuflor®, Schering-Plough Animal Health Corp., NADA 141-063 by the following characteristic(s): The generic product will have a different strength (concentration) from the pioneer.
Action:	Filed on March 18, 2004.